REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 1-7, 13-32, 39-41, 44, 45, and 48-55 remain pending in the application; however, Claims 23-25, 27-32, 45, and 48-55 remain withdrawn from consideration as a result of the previously issued Restriction Requirement. The Office maintains rejections under 35 USC § 102 and 35 USC § 103. The Office also maintains objections as to form.

The Office maintains an objection to Claim 44, based on the two periods which appear after a and b. With the instant Amendment, the terms "a." and "b." have been deleted from Claim 44.

Claims 1-3, 6-7, 14-22, and 39-40 remain rejected as being anticipated under 35 USC § 102(b) by the disclosure of Parsons, et al. (WO 01/98253). It is the position of the Office that Parsons, et al. disclose an example of solution for injection which is preservative free (i.e., Example 4, which contains an active ingredient, sodium chloride and water) and that Parsons, et al. also disclose neramexane and the hydrochloride salt of neramexane as active ingredients. The Office states that one skilled in the art would "immediately envisage" a solution of Example 4 wherein neramexane or neramexane hydrochloride is used as the active ingredient and that, therefore, the instant claims are anticipated by the disclosure of the Parsons, et al. reference.

With the instant Amendment, Claim 1 has been amended to recite "an aqueous based pharmaceutical composition for oral administration...". Support for this amendment may be found at page 4 of the specification, and the Applicants respectfully submit that no new matter has been introduced by this Amendment. The Applicants respectfully submit that the Parsons, et al. reference clearly does not disclose such compositions and, therefore, the instant claims, as amended, are not anticipated by the disclosure of this reference. Reconsideration and withdrawal of the anticipation rejection under 35 USC § 102(b) is respectfully requested.

Claims 1, 4-5, and 39-41 remain rejected for obviousness under 35 USC § 103(a) based on the disclosure of the above-mentioned Parsons, et al. reference. The Office states that no arguments rebutting this obviousness rejection were presented in the previous Response, and that, therefore, the rejection is maintained based on the reasons of record.

In the Response dated August 14, 2008, the Applicants stated the following with respect to the obviousness rejection (see page 5 of the Response):

> The Applicants respectfully submit that there is no teaching in the Parsons, et al. disclosure to suggest the surprising/unexpected anti-microbial properties associated with neramexane, which properties are disclosed in the instant specification, for example, at pages 25-27. The specification also discloses (at page 16) that such properties provide advantages over conventional formulations in terms of tolerability and safety since the microbial quality of the composition is provided by the active ingredient itself. Therefore, in view of the surprising and unexpected effects associated with the instantly claimed compositions, the disclosure of the Parsons, et al. reference, alone or in combination with the disclosure of the Gupta, et al. reference does not render the instantly claimed ***preservative free*** compositions obvious.

Moreover, the Office acknowledges the above-mentioned argumentation with respect to the maintained combination rejection discussed below. Thus, the Applicants respectfully submit that the Office has overlooked the fact that the argumentation rebutting the Parsons, et al. reference was directed to the rejection based on the disclosure of this reference ***alone or in combination*** with the Gupta, et al. reference. The Office's prejudicial refusal to consider this rebuttal, which was clearly of record in the last response, has necessitated the instant reiteration thereof.

Claims 1, 13, 26, and 44 also remain rejected for obviousness under 35 USC § 103(a) based on the disclosure of Parsons, et al. in view of Gupta, et al. (US Published Application No. 2005/0014743). As noted above, the Office acknowledges the argumentation submitted with the Response dated August 14,

2008 that there is no teaching in the Parsons, et al. reference to suggest the surprising/unexpected effects associated with neramexane; however, it is the position of the Office that the instant specification does not demonstrate such effects.

With respect to the relied upon disclosure at pages 25-27 of the instant specification, it is the position of the Office that this disclosure is related to memantine mesylate rather than neramexane mesylate. The Office goes on to provide an illustration as to the structural differences between memantine and neramexane. The Office further states "[a]pplicant is invited to provide evidence of unexpected results for neramexane mesylate, to demonstrate the position argued."

The Applicants respectfully reiterate that Example 4 at page 25 of the instant specification discloses that preservative free ***neramexane mesylate*** samples were prepared and then tested (according to the protocol described in Example 1) and that the results are shown in Tables 7-10 as well as the fact that "the results demonstrate that all tested solutions were microbiologically stable and effectively preserved against microbial contamination." The Applicants also note that the table headings for Tables 7-10 contain an obvious typographical error, referring to memantine rather than neramexane; however, the Applicants further submit that it would be clear to one of ordinary skill in the art, based on the description in Example 4, that the data in Tables 7-10 refer to neramexane mesylate formulations and not memantine mesylate formulations. With the instant Amendment, the specification has been amended to correct the table headings. The Office is invited to reconsider the Applicants demonstration of unexpected results.

Moreover, Example 10 at pages 37-38 of the instant specification discloses data demonstrating the antibacterial effectiveness of preservative free neramexane oral solutions, which provision of unexpected results has always been of record in the instant application. Thus, the Applicants respectfully request that the Office consider the previously submitted argumentation in view of the data disclosed in the instant specification, which data clearly demonstrate the superior/unexpected effects associated with neramexane.

In view of the Office refusal to consider the previously submitted argumentation, the Applicants submit contemporaneously with the instant Response a Petition for withdrawal of the Finality of the instant Office Action.

Moreover, the Applicants respectfully reiterate that there is no teaching in the Parsons, et al. disclosure to suggest the surprising/unexpected anti-microbial properties associated with neramexane, which properties are disclosed in the instant specification. Therefore, in view of the surprising and unexpected effects associated with the instantly claimed compositions, the disclosure of the Parsons, et al. reference, ***alone or in combination*** with the disclosure of the Gupta, et al. reference does not render the instantly claimed ***preservative free*** compositions obvious.

Reconsideration and withdrawal of the obviousness rejections under 35 USC § 103(a) is respectfully requested.

With respect to the previously issued Restriction Requirement, the Applicants respectfully reiterate that the instant invention, as amended, involves unity since the "special common technical feature" is a preservative free aqueous-based neramexane composition for oral administration. Moreover, in accordance with MPEP § 821.04, the Applicants respectfully request rejoinder of withdrawn Claims 23-25 and 27-32 upon the identification of allowable subject matter.

Withdrawn species Claims 45 and 48-55 have been cancelled without prejudice to the prosecution of the cancelled subject matter in a Divisional application.

Finally, with the instant Response, the Applicants also submit an Information Disclosure Statement which, it is respectfully submitted, should materially advance and accelerate the prosecution of the above-identified application. It is respectfully requested that the information be expressly considered during the prosecution of this application and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

As will be noted, this Information Disclosure Statement calls a number of references, which might be considered relevant, to the attention of the Examiner. The fact that these references are in fact "Prior Art" is, however, not admitted.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR § 1.98 and the Examiner is respectfully requested to consider the listed references.

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Accordingly, entry of present amendment, entry and acknowledgment of the IDS, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned agent has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call her at her below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By: _____

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Enclosure: Form PTO-1449 and Accompanying Reference; Check No. 76913 in the amount of $180.00 for IDS Fee; Amendments to the Specification; Listing of Claims; and Postal Card Receipt

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.